11 February, 1998

1476 '98 FEB 18 A9:49

Dockets Management Branch
HFA-305
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: Docket No. 97N-0477, Refurbishers, Rebuilders, Reconditioners, Servicers, and "As Is" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information

Enclosed are my comments, as requested in the Federal Register Notice identified above, on this ANPR. My comments are listed in tabular form, immediately beside the text of the Federal Register Notice.

If you are in need of any clarification, please do not hesitate to either call or fax me at the numbers below. Thank you.

John W. Smith
Director, Regulatory Affairs and Quality Assurance

97N-0477

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Refurbishers, Rebuilders, Reconditioners, Servicers, and "As Is" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information

[Federal Register: December 23, 1997 (Volume 62, Number 246)]
[Proposed Rules]
[Page 67011-67013]
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Proposed Rules

Federal Register

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 801, 803, 804, 806, 807, 810, 820, 821, 1002, and 1020
[Docket No. 97N-0477]
RIN 0910-ZA09
Refurbishers, Rebuilders, Reconditioners, Servicers, and "As Is" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information
AGENCY: Food and Drug Administration, HHS.
ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to review and, as necessary, to revise or to amend its compliance policy guides and regulatory requirements relating to the remarketing of used medical devices and the persons who refurbish, recondition, rebuild, service, or remarket such devices. The agency is considering these actions because it believes evolving industry practices warrant reevaluation of current policy and the application of certain regulatory requirements in order to ensure that particular remarketed devices meet suitable performance requirements for their intended uses, and are as safe as the originally marketed finished device. FDA is soliciting comments, proposals for alternative regulatory approaches, and information on these issues. In a future issue of the Federal Register, FDA will announce an open meeting of the Good Manufacturing Practices (GMP) Advisory Committee concerning these matters.
DATES: Written comments by March 23, 1998.
ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

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FOR FURTHER INFORMATION CONTACT: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4692.

Text of Federal Register Notice	Comments
SUPPLEMENTARY INFORMATION *I. Background* Medical device marketing has always involved a certain amount of remarketing of used medical devices that were refurbished, rebuilt, serviced, reconditioned, cosmetically enhanced or marketed ``as is" for further use. Under regulations issued by FDA for medical devices, including radiation emitting electronic products, at parts 801, 803, 804, 806, 807, 810, 820, 821, 1002, and 1020 (21 CFR parts 801, 803, 804, 806, 807, 810, 820, 821, 1002, and 1020), most such processing of used devices falls within the definition of manufacturing or is identified among activities performed by manufacturers, thereby subjecting remarketers to the same regulatory requirements as other manufacturers. These requirements include: labeling (part 801); medical device reporting (parts 803 and 804); corrections and removals (part 806); registration, listing and premarket notification (part 807); physician, patient notification and recall remedies (part 810); current good manufacturing practices (part 820); device tracking (part 821); and for electronic devices, electronic product reports (part 1002); and electronic product performance standards (part 1020).	

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Remarketing used devices may consist of activities that significantly change the finished device's performance or safety specifications, or intended use. These types of activities constitute ``remanufacturing" as defined in the Quality System regulation (QS) (also known as the current good manufacturing practice (CGMP) regulation) (Sec. 820.3(w)). Remarketing used devices can also consist of activities that do not significantly change the finished device's performance or safety specifications, or intended use. These activities may consist of refurbishing, reconditioning, rebuilding, servicing the device, or merely selling the device ``as is." Current guidance, discussed further in section II of this document, describes whom FDA considers a reconditioner or rebuilder of a device. FDA has not issued regulations or guidance defining what activities are considered ``servicing" or ``refurbishing." *II. Current Compliance Policy Guides Relating to Remarketers Who Are Considered Reconditioners, Rebuilders, and X-Ray Tube Reloaders* FDA has issued two compliance policy guides (CPG's) that relate to persons who remarket devices, but do not change the finished device's intended use. On November 1, 1981, FDA issued CPG 7133.20, which set forth the agency's position that ``adequate enforcement can be effectively accomplished" by considering reloaders of x-ray tube housing assemblies to be assemblers of x-ray components if a reloaded x-ray tube housing assembly is the only finished device produced by the firms. This CPG further stated reloaders must retain complaint files, injury reports, and failure analysis records that must be available for inspection by the agency. FDA has exercised its enforcement discretion with respect to establishment registration and device listing requirements under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) for such firms.	

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On December 29, 1987, FDA issued CPG 7124.28 to address the application of certain requirements of the act and its implementing regulations to firms that acquire and process used devices for remarketing purposes. The agency identified the reconditioner/rebuilder of a medical device as ``a person or firm that acquires ownership of used medical devices and restores and/or refurbishes these (devices) to the device manufacturer's original or current specifications, or new specifications, for purposes of resale or commercial distribution." In CPG 7124.28, the agency stated that reconditioners/rebuilders of medical devices must comply with: The registration, and premarket notification requirements of the act (section 510) and implementing regulatory requirements (part 807); the labeling requirements of the act (section 502) and applicable regulatory requirements (part 801); the CGMP requirements of the act (section 520) and implementing regulatory requirements (part 820); and, the medical device reporting requirements of the act (section 519) and implementing regulatory requirements (part 803). FDA intends to revise this CPG based on FDA's experience in this area and the comments received to this advance notice of proposed rulemaking (ANPR). *III. Reasons for Review* In the Federal Register of October 7, 1996 (61 FR 52602), FDA issued a revised QS regulation which set forth CGMP requirements for medical devices (part 820). The preamble of the October 7, 1996, QS regulation acknowledged that: [CPG] 7124.28 contains the agency's policy regarding the provisions of the act and regulations with which persons who recondition or rebuild used devices are expected to comply. This CPG is in the process of being revised in light of FDA's experience in this area. FDA is not including the terms ``servicer" or ``refurbisher," as they relate to entities outside the control of the original equipment manufacturer, in this [QS] final regulation, even though it believes that persons who perform such functions meet the definition of manufacturer.(61 FR 52602 at 52610)	

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FDA further advised that, ``[b]ecause of a number of competitive and other issues, including sharply divided views among members the GMP Advisory Committee at the September 1995 meeting, FDA has elected to address application of the GMP requirements to persons who perform servicing and refurbishing functions outside the control of the original manufacturer in a separate rulemaking later this year'' Id. In addition to the concerns raised in the QS/CGMP rulemaking process relating to the applicability of CGMP's to remarketers, issues have been raised relating to the applicability of other regulatory requirements to remarketers. In response to these concerns, FDA has attempted to learn more about the concerns relating to remarketers. In 1994, FDA began discussing issues related to remarketers with the International Association of Medical Equipment Remarketers (IAMER). Beginning in 1994 and continuing through IAMER's April 10 to 12, 1997, meeting, representatives of the FDA's Center for Devices and Radiological Health have attended, and on occasion made presentations at, various meetings and conferences of IAMER membership firms. Through exchanges at these meetings and correspondence with IAMER's Regulatory Affairs Committee, FDA has preliminarily noted that rising costs and health care expenses have apparently contributed to expanded sales of a growing variety of remarketed devices. Much of this activity is occurring outside the control of the original equipment manufacturer. FDA also tentatively concluded that a significant number of firms that have been refurbishing or otherwise remarketing electronic radiation emitting medical devices are unaware of FDA's compliance policy, and the applicable regulations and statutory requirements, such as the filing of initial and other reports under parts 1002 and 1020, with respect to their activities.	

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IV. Proposed Definitions of Remarketing Activities That Constitute Refurbishing, ``As Is'' Remarketing, and Servicing	
As stated in section II of this document, FDA has issued guidance, which is being considered for revision, that describes who FDA considers to be ``reconditioners'' and ``rebuilders.'' FDA has not issued regulations or guidance defining what persons are considered to be ``refurbishers,'' ``as is'' remarketers, or ``servicers.'' These terms have been difficult to define and at times have been used interchangeably. Compliance Policy Guide 7124.28 states only that FDA considers rebuilders or reconditioners to be persons who have acquired ownership of the devices and conduct refurbishing activities.	I agree that further definition of these terms is required.
FDA is soliciting comments on whether to propose definitions, as described in the following three paragraphs, of types of remarketers, either in guidance or in a regulation, that may or may not relate to the ownership of the devices. Accordingly, FDA is soliciting comments on whether it should propose by regulation, or issue by guidance, the following definitions or a variation of these definitions to describe remarketing activities that do not significantly change a finished device's performance or safety specifications or intended use.	The effort to define the terms under question is appreciated. CPG 7124.28 is unclear on these terms. I recommend a regulation, *very carefully* defining the terms (see comments below), and defining which parts of the Act apply. From a pragmatic standpoint, any guidances in this area will be subject to varying interpretations, with many servicing organizations not recognizing the applicability of the relevant portions of the Act to them. Therefore, a regulation should be the preferred enforcement mechanism. Much of this Federal Register Notice is predicated on the assumption that refurbishers, "as-is" remarketers and servicers do not "significantly change a finished device's performance or safety specifications or intended use." Please add text explaining what "significant" changes are, possibly lifting from 21 CFR, part 807.81(a)(3)(i).

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Refurbishers: persons who, for the purpose of resale or redistribution, visually inspect, functionally test and service devices, as may be required, to demonstrate that the device is in good repair and performing all the functions for which it is designed. The device may or may not be cosmetically enhanced. Preventive maintenance procedures may or may not be performed. Refurbishers do not significantly change a finished device's performance or safety specifications, or intended use.	The definition of refurbisher is unclear: 1. What is the difference between a refurbisher and a servicer (as defined below)? Both appear to perform preventive maintenance, or otherwise service devices to return them to "fitness for use" specifications. Better distinction between the two should be made, or they should be grouped into one term. 2. Is re-sterilization (i.e., of a single-use device) included under the definition of "preventive maintenance procedures" or "service", as specified in this particular definition?
"As Is" Remarketers: for the purpose of resale or redistribution, the operational condition of the device is unknown. The extent to which the device meets the operational requirements must be determined by the user prior to patient exposure. The device may or may not be cosmetically enhanced. ``As Is" remarketers do not change a finished device's performance or safety specifications, or intended use.	
Servicers: persons who repair a device to return it to the manufacturer's fitness for use specifications, and perform the manufacturer's recommended scheduled preventive maintenance. Servicers do not significantly change a finished device's performance or safety specifications, or intended use.	The definition of servicer is unclear: 1. What is the difference between a servicer and a refurbisher(as defined above)? Both appear to perform preventive maintenance, or otherwise service devices to return them to "fitness for use" specifications. Better distinction between the two should be made, or they should be grouped into one term. 2. Is re-sterilization of a device included under the definition of "returning a device to the manufacturer's fitness for use specifications" or "preventive maintenance", as specified in this particular definition?

[redacted]

specifications, or intended use, and is reassessing the degree of regulatory control necessary to ensure the protection of the public health. FDA intends to evaluate the current regulatory approach with respect to remarketers who are refurbishers, ``as is'' remarketers, and servicers, as defined in this document, and is soliciting comments on whether FDA should retain the current regulatory approach, or whether the agency should use alternative approaches to regulate these types of remarketers.

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The agency believes that any regulatory approach for these types of remarketers should, at a minimum, include compliance with requirements concerning: Representations of quality under section 501(c) of the act (21 U.S.C. 351(c)); false or misleading labeling under section 502 of the act (21 U.S.C. 352), and part 801; notification and recall provisions under section 518 of the act (21 U.S.C. 360h), and part 810; corrections and removal reporting requirements under section 519(f) of the act (21 U.S.C. 360i(f)), and part 806; medical device reporting under section 519(a) of the act, and parts 803 and 804; tracking requirements under section 519(e) of the act, and part 821; and radiological health requirements under sections 532 through 542 of the act (21 U.S.C. 360ii through 360ss), including records and initial reporting requirements under part 1002, and standard requirements under part 1020.	I agree with these minimum requirements.
Accordingly, FDA requests information on the following issues relating to remarketing activities that do not significantly change the finished device's performance or safety specifications or intended uses.	
(1) Has FDA appropriately defined the terms, ``refurbisher,'' ``as is'' remarketers, and ``servicers''? If not, what changes to these definitions should be made?	The definitions are inadequate. See comments above. Recommendations for consideration when re-writing the definitions: 1. Consider how third-party organizations differ from in-house service (i.e., biomedical engineering) departments. 2. Consider where re-sterilization of single-use devices fits in these definitions. Is it refurbishing, servicing, or reconditioning / rebuilding? 3. Does device ownership play a role in the definitions?
(2) What evidence exists regarding actual problems with the safety and/or performance of remarketed devices that are the result of the remarketing? Specific examples should be submitted.	This company has experienced a reportable adverse event when one of its terminally sterilized, single-use laparoscopic electrodes, after "three or four" re-sterilizations, broke during use, requiring surgical intervention. Had the device not been re-processed, the adverse event would not have occurred.
(3) What is the appropriate level of regulatory controls that should be applied to persons who remarket devices?	As stated in the comments above, a regulation should be initiated, clearly defining the terms and defining which parts of the Act apply.

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(4) Should refurbishers, "as is" remarketers, and servicers be subject to the same or different regulatory requirements?	The regulatory requirements should be only slightly different - see comments below.
In addition, FDA is specifically considering whether to propose rulemaking regarding modified registration, listing, and CGMP requirements for these types of remarketers, or whether to make some or all of the these three controls voluntary. For example, the agency could propose that refurbishers and/or servicers be required to register and list with FDA (part 807), and comply with certain CGMP requirements, such as quality system requirements (part 820, subpart B), production and process controls (part 820, subpart G), acceptance activities (part 820, subpart H), corrective and preventive action (part 820, subpart J), labeling and packaging control (part 820, subpart K), and records (part 820, subpart M). Alternatively, the agency could propose that refurbishers and/or servicers be required to register and list, but comply only with CGMP requirements for maintaining complaint files (Sec. 820.198(a)) and conducting failure analyses (Sec. 820.198(b) and (c)). In making comments relating to the regulatory approaches, comments should indicate whether their comments relate to refurbishers, ``as is" remarketers, and/or servicers, as described in section IV of this document. Other regulatory approaches may be proposed by the agency or by the comments which, if implemented, would require the issuance of new guidance documents, or consist of changes to current regulations or changes to existing guidances CPG 7124.28 and CPG 7133.20.	I recommend that, at a minimum, all three of these types of remarketers (as well as reconditioners / rebuilders) be subject to a subset of the CGMP (and other) regulatory requirements: 1. Management responsibility 2. Quality system, quality policy 3. Training 4. Servicing 5. Process Control (and validation, if re-sterilization is included in the scope of the definitions) 6. Internal quality audits 7. Preventive & corrective action 8. Inspection and testing 9. Control of nonconforming product 10. Quality records 11. Complaints 12. Medical Device Reporting (MDR) 13. Corrections / Recalls 14. Premarket Approval / Premarket Notification This level of control will provide the public adequate assurance that, once out of a device manufacturer's control, medical devices continue to be safe and effective, as designed by the manufacturer, and as cleared for US marketing by FDA. Revision to CPG 7124.28 should also be considered, clarifying the definitions of reconditioners / rebuilders, specifically towards identifying to what extent those definitions include the re-sterilization of devices.

VI. Comments

The agency will consider any comments submitted in response to this ANPR, or comments relating to the reevaluation of agency guidances, including CPG's 7124.28 and 7133.20. FDA will consider the record of any public meetings or any advisory committee meetings, along with comments, proposals and other information received, when deciding whether to issue or revise agency guidance or modify any existing regulations.

Interested persons may, on or before March 23, 1998 submit to Dockets Management Branch (address above) written comments regarding this ANPR. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA does not anticipate granting requests for extension to this 90-day comment period.

Dated: December 3, 1997.
William K. Hubbard,
Associate Commissioner for Policy Coordination.
[FR Doc. 97-33372 Filed 12-22-97; 8:45 am]
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(Updated December 23, 1997)

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